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ISSUES

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Rapid HIV Tests: Issues for Program & Clinic Managers

What are rapid HIV tests?

A rapid HIV test is a screening test for detecting antibody to HIV that produces very quick results, usually in 5 to 30 minutes. The only rapid HIV test licensed by the Food and Drug Administration (FDA) that is commercially available in the United States is the Single Use Diagnostic System for HIV-1 (SUDS), manufactured by Murex Corporation*. However, other tests – several of which are simpler to perform – may become available soon.

What are the likely benefits from the use of rapid HIV tests?

The use of rapid tests can enhance HIV prevention services for your clients. Rapid tests allow you to deliver test results and counseling to more people, because you can provide results on the day of testing. Therefore, you can communicate HIV test results to everyone who is tested and advocate additional HIV prevention strategies.

HIV negative clients can be assured of their negative status and be counseled accordingly. Persons whose rapid tests are reactive+ can be counseled about the likelihood of being infected and the need for behavioral precautions until confirmatory testing has been performed. Specifically, the client needs to be informed that after a person is infected with HIV, it takes time (average, 25 days) before antibodies develop that can be detected by an HIV antibody test.[1]

Experience with using rapid tests in a sexually transmitted disease (STD) clinic demonstrated that most persons who receive a reactive rapid test result return for their confirmatory test results on their own, reducing the need for field visits. Thus, using rapid HIV tests is likely to mean that your facility will experience more clinic-based counseling visits and fewer field visits.

Should you implement rapid HIV testing in your setting?

The benefits of rapid testing are greatest for clinics that serve a population with a high prevalence of HIV but have experienced low rates of return for HIV test results. The higher the prevalence of HIV infection among those tested in your program, the higher the positive predictive value of a

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*Use of trade names is for identification only and does not imply endorsement by the Public Health Service or the U.S. Department of Health and Human Services

+"Reactive rapid test" as used in this document means a repeatedly reactive rapid test, i.e., the same test was performed twice and was reactive both times.

reactive rapid HIV test, i.e., the more likely that a reactive rapid test result means the person is actually infected with HIV. (See the Predictive Value appendix in "Issues for Counselors Providing HIV Prevention Counseling.") The predictive value may be further improved by considering each client's risk for HIV infection.[2] The predictive value of a reactive rapid HIV test result is much higher for clients with risk behaviors for HIV.

If many clients at your facility do not return for their test results, implementing rapid testing can help you increase the number of persons who receive their test results and appropriate counseling. You can also reduce the time that staff spends in conducting field visits.

What are the potential disadvantages to the use of rapid HIV tests?

Facilities that serve clients who have low behavioral risks for HIV infection and who come from communities with low HIV prevalence will experience a higher proportion of false-positive tests among clients whose rapid HIV test is reactive. At such sites, staff should consider carefully the distress that may be caused by false-positive results (see "Issues for Counselors Providing HIV Prevention Counseling"). These facilities may wish to offer rapid testing only to clients at increased risk of HIV infection.

Some sites may not wish to implement rapid testing or only offer it selectively. In facilities where most clients return for their test results, rapid tests may increase the costs, e.g., they are more expensive than EIAs, which are performed in batches in the lab. And finally, facilities that do not have access to on-site or nearby laboratory facilities will not be able to use the currently available SUDS test, because it requires an on-site laboratory to perform.

What type of laboratory is needed to perform rapid HIV tests?

The SUDS rapid test is classified as a test of moderate complexity. A laboratory and laboratory technician are required. Most labs which perform Rapid Plasma Reagin (RPR) tests for syphilis can become eligible to perform the SUDS test. Because the SUDS test uses serum or plasma, it requires a blood sample drawn from the vein, which must be centrifuged before testing. Factors such as temperature and centrifuge speed may also affect the test results.[3] Future rapid tests are expected to be simpler to perform.

What are the likely additional costs from the use of rapid HIV tests?

The cost of the rapid HIV test kits ($6 to $10) is usually more than that of a standard EIA ($1 to $2). The package insert for the SUDS test states that a positive control and a negative control should be run with each batch of tests. Therefore, the cost of rapid tests can be lowered when HIV tests can be run in batches because fewer test kits are needed for controls. However, if specimens are held until they can be run in batches, the rapid test may lose its main benefit – providing HIV test results rapidly.

Other costs include training, laboratory technician time, space in your facility for laboratory and counseling services, and the amount of counselor time needed for two counseling sessions per patient in one day. Cost savings include the potential decrease in field visits for follow-up and the potential decrease in the number of second visits for HIV counseling.[4]

How might rapid tests change the delivery of counseling and testing services?

Rapid tests may affect HIV counseling and testing services in your facility in several ways. However, procedures for partner notification and referrals for medical care will probably not change, because clients with a reactive rapid HIV test result still need to return to receive the results of a confirmatory test – a Western blot or immunofluorescence assay (IFA).

Depending on how rapid HIV testing is offered to clients, you might expect to see an increase in the numbers of persons who seek or accept HIV counseling and testing in your facility. However, you might also see a decrease in total client visits, since persons with a negative rapid HIV test result will not need to return.

You may need to alter the flow of clients through your facility by routing persons who are to be tested with rapid HIV tests first to HIV counseling and specimen collection services, to allow time for the laboratory to perform the test.

Persons who accept rapid HIV testing may have a longer stay in the clinic (waiting for specimens to be tested, especially if specimens are batched). In addition, counselors will spend more time with each client because there will be two contacts with each client in one day.

Rapid testing will change how and when HIV prevention counseling is delivered. (For information about providing counseling to clients with either negative or reactive results, see "Issues for Counselors Providing HIV Prevention Counseling.")

Record-keeping may need revision to accommodate new rapid HIV testing options, e.g., changes in forms. The software that many programs use for reporting HIV counseling and testing activities to CDC is being modified to allow programs to enter a test result with the same date as that of the initial clinic visit. This revised software will be distributed in the near future after field testing is complete.

What quality assurance systems are needed for rapid HIV testing services?

As is true for all diagnostic tests, quality assurance programs and proficiency testing should be part of routine laboratory practice. For the SUDS test, a positive control and negative control should be run to ensure accurate test performance. Some programs run these controls each day and with each new lot of test kits. CDC sponsors a proficiency testing program for evaluation of HIV antibody testing – the Model Performance Evaluation Program – and also sponsors the National Laboratory Training Network to train laboratory staff. (See Resources section for information.)

A quality assurance plan must be in place to ensure that appropriate, competent, and sensitive methods are used for risk assessments, counseling, and referral of clients.

How should rapid HIV testing services be evaluated?

As is true of any new program activity, an evaluation mechanism is needed to assess the efficiency and effectiveness (including cost-effectiveness) of using the rapid HIV test in your clinic, as well as the effect on your HIV prevention program. Your CDC project officer and the Program Evaluation Research Branch in CDC's National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention – Intervention Research and Support are available for consultation about program evaluation.

What is the future of rapid HIV testing?

Several other rapid HIV tests are being used in other countries. Other, simpler rapid HIV tests (including one for use with oral fluids) may soon become available for clinical use in this country. When additional rapid HIV tests become available, CDC will evaluate whether a combination of two different rapid tests may allow the confirmation of reactive test results on the day that clients are tested.

References

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3. Kassler WJ, Haley C, Jones W, et al. Performance of a rapid, on-site human immunodeficiency virus antibody assay in a public health setting. *J Clin Microbiol* 1995;33:2899-2902.

4. Farnham P, Gorsky R, Holtgrave D, et al. Counseling and testing for HIV prevention: costs, effects, and cost-effectiveness of more rapid screening tests. *Public Health Rep* 1996; 11:44-53

Resources

Model Performance Evaluation Program
CDC Public Health Practice Program Office
Division of Laboratory Systems
(770) 488-4147

National Laboratory Training Network
CDC Public Health Practice Program Office
Division of Laboratory Systems
(770) 488-7811

Program Evaluation Research Branch
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